

## REMARKS

Claims 21-47 are now pending in the application. Claims 21-47 stand rejected. Claims 1-20 have been previously cancelled. Claims 21, 24-26, 39, 43, 44 and 45 have been amended herein. Support for the amendments can be found throughout the application, drawings and claims as originally filed and, as such, no new matter has been presented. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### REJECTION UNDER 35 U.S.C. § 102

Claims 21-25 and 28-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Harari et al. (U.S. Pat. No. 6,328,744; hereinafter "Harari"). This rejection is respectfully traversed.

Initially, Applicants note that Harari discloses a bone boring device that includes rigid needles for boring through the bone. In Figs. 9A and 9B, Harari discloses that the boring device includes a needle 302 attached to a hinge via a needle arm 304. The needle 302 is rotatable to bore a curved channel through the bone. Harari discloses that the needles are pushed into the bone. In Figs. 17A-17B, Harari discloses two drill bits 504 coupled adjacent to needles 508, 520. The drill bits 504 are used to drill two linear apertures 540 in the bone, and the needles 508, 520 are used to form a curved bore 542 in the anatomy. In contrast to Harari, independent Claim 1 has been amended to recite:

positioning at least a portion of a **flexible** single shaft  
cutting tool **through a flexible guide mechanism**;  
positioning the **flexible** single shaft cutting tool  
adjacent to the bone structure at a first bone location;

**guiding the flexible single shaft cutting tool with a guide mechanism** from the first bone location to a second bone location; and

cutting a non-linear path through the bone structure so as to cause the **flexible** single shaft cutting tool to exit the bone structure at the second bone location (emphasis added).

Independent Claim 28 recites:

...interconnecting a **flexible drill shaft** and a drill head;

forming a small incision in a tissue near the bone structure;

passing the drill head with the **flexible** drill shaft percutaneously through the small incision;

drilling into the bone structure with the drill head;

**guiding the drill head with the flexible drill shaft with a guide mechanism** along a selected non-linear cutting path...(emphasis added).

In view of the above discussion, Applicants assert that Harari does not teach, suggest or disclose each and every element of Claims 21 and 28. With regard to Claims 21 and 28, Harari does not teach, suggest or disclose positioning at least a portion of a **flexible** single shaft cutting tool **through a flexible guide mechanism, guiding** the flexible single shaft cutting tool with the flexible guide mechanism from the first bone location to a second bone location or **guiding** the drill head with the flexible drill shaft with the guide mechanism along a selected non-linear cutting path. Rather, Harari teaches the use of rigid arcuate needles that are pushed into the bone and does not disclose whatsoever guiding the needles into the bone with a flexible guide mechanism. Further, Applicants note that one of ordinary skill in the art of bone boring would not look to modify Harari to include guiding the needles with a flexible guide

mechanism, as due to the fixed rigid shape of the needles, a flexible guide mechanism is not necessary.

With additional regard to Claim 28, Applicants note that Harari does not teach, suggest or disclose interconnecting a flexible drill shaft and a drill head, passing the drill head with the flexible drill shaft percutaneously through the small incision, guiding the drill head with the flexible drill shaft with a guide mechanism along a selected non-linear cutting path and forming the selected non-linear cutting path between an entering position and an exiting position spaced a distance from the entering position in the bone structure. In this regard, Harari teaches merely using rigid, non-flexible drill bits 504 to cut a linear path in the bone. Applicants further note that drill bits 504 do not include a flexible drill shaft as claimed.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that Harari does not teach, suggest or disclose each and every element of Claims 21 and 28, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of Claims 21 and 28 under 35 U.S.C. § 102(b).

In addition, since Claims 22-24 and 29-34 depend directly or indirectly from either independent Claim 21 or 28, Claims 22-24 and 29-34 should be in condition for allowance for at least the reasons set forth for Claims 21 and 28 above. Further, Applicants note that Claim 29 includes independently allowable subject matter as Harari does not teach, suggest or disclose engaging the suture with a suture mechanism near the drill head. Additionally, Claim 30 is believed to have independently allowable subject matter as Harari does not teach, suggest or disclose a guide mechanism that includes a flexible rod at least partially enclosing at least a portion of the flexible drill

shaft that is coupled to the flexible drill shaft at a proximal end. Claim 31 is also believed to have independently allowable subject matter as Harari does not teach, suggest or disclose positioning at least a portion of the flexible drill shaft through a flexible rod, connecting a flexible member to a portion of the flexible drill shaft and sliding a handle to tension the flexible member to assist in directing the flexible drill shaft along the selected non-linear path.

With regard to Claim 32, Applicants also note that Claim 32 is believed to have independently allowable subject matter as Harari does not teach, suggest or disclose that sliding the handle to tension the flexible member moves the flexible member to engage the drill head or the flexible drill shaft to move the drill head from the selected first path to the selected second path during forming the selected non-linear cutting path. Claim 33 is also believed to have independently allowable subject matter as Harari does not teach, suggest or disclose directing at least one of the flexible drill shaft, the drill head or combinations along a first path and directing at least one of the flexible drill shaft, the drill head or combinations along a second path.

Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 22-24 and 29-34 under 35 U.S.C. § 102(b).

#### **REJECTION UNDER 35 U.S.C. § 103**

Claims 26 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari. This rejection is respectfully traversed.

Since Claims 26 and 35 depend directly from either independent Claim 21 or 28, Claims 26 and 35 should be in condition for allowance for at least the reasons set forth

for Claims 21 and 28 above. Further, Applicants note that Claim 26 includes independently allowable subject matter as Harari does not teach, suggest or disclose directing the single shaft cutting tool in the non-linear path with a rod formed of a memory-shape alloy. In this regard, as discussed, Harari does not teach whatsoever guiding the needles into the bone with a guide mechanism, such as a rod formed of a memory-shape alloy. Applicants note that one of ordinary skill in the art of bone boring would not look to modify Harari to include directing the needles with a rod formed of a memory-shape alloy, as due to the fixed, rigid shape of the needles, a flexible guide mechanism is not necessary. Similarly, Claim 35 is believed to include independently allowable subject matter as Harari does not teach, suggest or disclose a flexible guide mechanism that includes a flexible rod made from a shape memory alloy. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 26 and 35 under 35 U.S.C. § 103(a).

Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari in view of Moore et al. (U.S. Pat. No. 4,872,451; hereinafter "Moore"). This rejection is respectfully traversed.

Applicants note that Claim 27 depends directly from independent Claim 21, and thus, Claim 27 should be in condition for allowance for at least the reasons set forth for Claim 21 above. In this regard, Applicants note that Moore does not provide any further teachings that overcome the shortcomings of Harari, which were identified in the remarks regarding Claim 21, above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejection of Claim 27 under 35 U.S.C. § 103(a).

Claims 36-41 and 43-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari further in view of Hyde (U.S. Pub. No. 2002/0095214; hereinafter "Hyde"). This rejection is respectfully traversed.

Applicants respectfully refer the Office to the remarks regarding Claims 21-25 and 28-34 for a discussion of the Harari reference. With regard to Hyde, Applicants note that Hyde discloses a transosseous core approach to access an articulating surface. Hyde teaches drilling a core through a first bone A with a non-articular surface 8A such that the core or bone hole CH1 is adjacent to an articular surface 1A of a second bone B. The drilling of the bone hole CH1 enables the treatment of the articular surface 1A as tools can pass through the bone hole CH1. Hyde does not teach, suggest or disclose the use of any type of guide mechanism to form the bone hole CH1, let alone the use of a flexible guide mechanism. In contrast to Harari and Hyde, independent Claim 39 recites:

...drilling into the identified bone structure with a drill head associated with a flexible drill shaft;  
**guiding the drill head with a flexible guide mechanism** through an entry position and through the identified bone structure in a first direction...(emphasis added).

In view of the above discussion, Applicants assert that none of the cited references, singly or in combination, teach, suggest or disclose each and every element of Claim 39. In this regard, as discussed, Harari does not teach, suggest or disclose **guiding** a drill head (associated with the flexible drill shaft) with a **flexible guide mechanism** through an entry position and through the identified bone structure in a first

direction. Rather, Harari teaches the use of rigid arcuate needles that are pushed into the bone and does not disclose whatsoever guiding the needles into the bone with a flexible guide mechanism, as discussed. Hyde does not remedy this shortcoming of Harari. Hyde merely discloses the formation of one or more bone holes in an anatomy to reach an articular surface. In addition, Applicants note it is improper to modify Harari with Hyde as this modification would change the principle of operation of the bone boring system of Harari. Further, Applicants note that one of ordinary skill in the art of bone boring would not look to modify Harari to include guiding the needles with a flexible guide mechanism, as due to the rigid, fixed shape of the needles, a guide mechanism is not necessary.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that Harari and Hyde, singly or in combination, do not teach, suggest or disclose each and every element of Claim 39, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of Claim 39 under 35 U.S.C. § 103(a).

In addition, since Claims 36-38, 40, 41 and 43-47 depend directly or indirectly from either independent Claim 28 or 39, Claims 36-38, 40, 41 and 43-47 should be in condition for allowance for at least the reasons set forth for Claims 28 and 39 above. Further, Applicants note that Claim 38 includes independently allowable subject matter as the cited art does not teach, suggest or disclose associating a suture engaging hook with the drill head. Additionally, Claim 43 is believed to have independently allowable subject matter as the cited art does not teach, suggest or disclose a flexible guide mechanism that includes a flexible rod that is coupled to the flexible drill shaft at a proximal end. Claim 44 is also believed to have independently allowable subject matter

as the cited art does not teach, suggest or disclose connecting a flexible member to a portion of the flexible drill shaft and sliding a handle to tension the flexible member to direct the flexible drill shaft along the selected curved path while forming the tunnel.

Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 36-38, 40, 41 and 43-47 under 35 U.S.C. § 103(a).

Claim 42 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari in view of Hyde and further in view of Moore. This rejection is respectfully traversed.

Applicants note that Claim 42 depends directly from independent Claim 39, and thus, Claim 42 should be in condition for allowance for at least the reasons set forth for Claim 39 above. In this regard, Applicants note that Moore does not provide any further teachings that overcome the shortcomings of Harari and Hyde, which were identified in the remarks regarding Claim 39, above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejection of Claim 42 under 35 U.S.C. § 103(a).

#### **CONCLUSION**


It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner



believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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By:   
Richard W. Warner, Reg. No. 38,043  
Erica K. Schaefer, Reg. No. 55,861

HARNESS, DICKEY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

RWW/EKS/chs